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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,721	02/12/2001	William Richard Dubrul	ARTM 1008-5 US	8945

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EXAMINER

SERKE, CATHERINE

ART UNIT	PAPER NUMBER
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3763

19

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/781,721

Applicant(s)

DUBRUL ET AL.

Examiner

Catherine Serke

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 26, 28-30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Shapland et al (US '306).

Shapland discloses a polymer matrix drug delivery apparatus that includes a porous tubular mesh (82) comprising a contact-dispensable agent and a radially expandable element (84) where the dispensing of the agent is carried out by iontophoresis (see figs 8a-8b). While Shapland does not disclose the method steps as claimed, all the method steps are considered inherent for the use of the prior art device as disclosed.

Claims 34-36 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Theron (US '2000).

Theron discloses a balloon catheter for stent implantation that includes the steps of first positioning an inflatable balloon at a target site in the body; next inflating the balloon, deflating the balloon and displacing the balloon, then positioning at the target site an axially compressible, radially expandable tubular braid scaffolding mounted to the catheter shaft at a second position

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on the catheter; and finally expanding the tubular braid (see figures 1, 4 and 5). See also column 4 lines 20+, 53+ and column 5 lines 1+.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland in view of Wolff et al.

Shapland meets the claim limitations as described above but fails to include a braid as the tubular mesh. At the time of the invention, it would have been obvious to have the porous mesh of Shapland be in the form of a braid since tubular braid stents are well known in the art and are used for their mechanical strength. Wolff discloses use of such braid. At the time of the invention it would have been obvious to incorporate the braid of Wolff into the invention of Shapland in order to provide a mesh with enhanced strength.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theron in view of Wolff et al.

Theron meets the claim limitations as described above but fails to include dispensing an agent from the scaffolding. At the time of the invention, it would have been obvious to have the porous mesh of Theron be capable of eluting a drug agent since administering drugs to the walls of blood vessels after angioplasty and /or stenting is well known in the art and done in order to

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increasing the time the vessel wall will remain patent. Wolff discloses use of such a scaffolding. At the time of the invention it would have been obvious to incorporate the scaffolding of Wolff into the invention of Theron in order to provide a scaffolding that will increase the effectiveness of the angioplasty and stenting to the patient.

### ***Response to Arguments***

Applicant's arguments filed 3/11/03 have been fully considered but they are not persuasive. Applicant argues that the hydrogel matrix of Shapland does not read on the porous tubular mesh as claimed. The examiner disagrees with this argument. Shapland discloses that the hydrogel matrix is both a tube and porous (see Remarks: Cited art in Response dated 3/11/03). Additionally, a hydrogel is by structure a mesh of copolymers on the molecular level. A mesh is defined as "an interlocking or intertwining arrangement or construction". Merriam Webster's Collegiate Dictionary, 10th ed.

Applicant argues that the stent of Theron is not an axially compressible, radially expandable tubular braided scaffolding. However, figures 1, 4 and 5 show the stent in a woven (braid) configuration. Additionally as shown, the stent is self expanding which inherently means that when the structure radially expands (as shown in the drawings) the structure will have to shorten in length (axially compressible) in order for the radial expansion to occur.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke   
May 28, 2003

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700